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2016 APR 21 PM 12:26

April 21, 2016

Writer's Direct Access  
**John B. Dubeck**  
(202) 434-4125  
dubeck@khlaw.com

**Via Hand Delivery**

**CBIC Control Number**  
**368996**

TSCA Confidential Business Information Center (7407M)  
Attn: Section 8(e)  
U.S. Environmental Protection Agency  
1201 Constitution Avenue, NW  
WJC East - Room 6428  
Washington DC 20004-3302

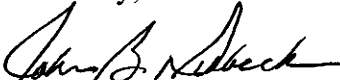
**Re: TSCA 8(e) Submission for Chemical Abstracts Service Registry Numbers  
(CASRN)s 375-95-1, 335-67-1, 1763-23-1, 335-76-2, 2058-94-8, and 355-  
46-4; Withdrawal of Confidential Business Information Claims**

Dear Sir or Madam:

On behalf of our client, Solvay Specialty Polymers USA, LLC (Solvay), we are refiling a submission to the U.S. Environmental Protection Agency (EPA) that was made pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA) (15 U.S.C. § 2601 *et seq.*). This filing was dated March 26, 2016, and concerns the substance perfluorononanoic acid (PFNA, CASRN 375-95-1) and several other perfluorinated chemicals (PFCs). Based on discussions with EPA staff in the Office of Pollution Prevention and Toxics, our client is withdrawing the confidential business information (CBI) claims for this submission. We have enclosed a copy of this submission with the CBI claims removed; the content of the submission is otherwise unmodified.

If you have any questions or require additional information on this matter, please do not hesitate to contact me.

Sincerely,

  
John B. Dubeck

Enclosure



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**VIA FEDEX**

March 24, 2016

TSCA Confidential Business Information Center (7407M)

WJC East - Room 6428

Attn: Section 8(e)

U.S. Environmental Protection Agency

1201 Constitution Avenue, N.W.

Washington, D.C. 20004-3302

[Confidentiality claim removed]

**Re: TSCA 8(e) Submission; Chemical Abstract Services Registry Numbers  
("CASRN") 375-95-1, 335-67-1, 1763-23-1, 335-76-2, 2058-94-8, and 355-46-4**

Dear Sir/Madam:

Solvay Specialty Polymers USA, LLC (Solvay) is making this submission to the U.S. Environmental Protection Agency (EPA) pursuant to Section 8(e) of the Toxic Substances Control Act ("TSCA", 15 U.S.C. § 2601 *et seq.*). Solvay recently became aware of certain human serum sampling results. These data confirm the well-known fact that a number of perfluorinated chemicals ("PFCs") have become widely dispersed in the environment to the extent that very low levels are present in essentially all human serum. The current data reveal that perfluorononanoic acid ("PFNA", CASRN 375-95-1) is present at levels over the national average in the serum of a small group tested. PFNA was previously used at Solvay's West Deptford, New Jersey, facility; the serum samples have been reported to Solvay as being from residents that obtained their drinking water from private wells in West Deptford Township. [Confidential explanation for prior claim of confidentiality removed.]

Solvay has received only limited information on the individuals tested. Solvay had no role in the selection of the individuals tested or the testing methodology employed. The results of this investigation are only applicable to the individuals tested. The results cannot be generalized to other populations and appear to represent data from two clusters that had distinctly different sources of exposure; whether the exposure of either or both is representative of the local environment is unknown. In addition, these results cannot be used to predict the future occurrence of disease or be associated with current or past health problems. Also, serum PFC concentrations do not provide information about the source of exposure (*i.e.*, water, soil, or food) or how the tested individuals vary with regard to their interactions with different potential exposure pathways.

Solvay is reporting these human serum data pursuant to section 8(e) of TSCA despite the fact that Solvay ceased use of PFNA in 2010 and believes it no longer has any obligation under TSCA section 8(e) for PFNA. These data are being submitted based solely on a 2006 EPA guidance document on TSCA section 8(e) reporting that "If the new information on a chemical known to have serious toxic effects indicates a level of exposure previously unknown to the Administrator, it should be reported. Information that corroborates known exposure levels, such as those within the range of chemical blood levels and other biological monitoring data recorded in the [CDC] NHANES (National Health and Nutrition Examination Survey) data base, is not reportable."<sup>1</sup> Consequently, it appears that EPA considers any serum sampling data in excess of the levels reported in the NHANES database as evidence of substantial risk even if those levels, while above the national background, are still so low as to not actually pose a substantial risk. For PFNA, the February 2015 Tables from CDC's *Fourth National Report on Human Exposure to Environmental Chemicals* show a geometric mean of 0.881 µg/L for the latest survey period, 2011-2012.<sup>2</sup>

The serum data obtained by Solvay represent only seven individuals. The PFNA result for each individual in the group exceeds the geometric mean of 0.881 µg/L for the 2011-2012 NHANES survey period. The serum data also include test results for perfluorooctanoic acid (PFOA, CASRN 335-67-1), perfluorooctane sulfonic acid (PFOS, CASRN 1763-23-1), perfluorodecanoic acid (PFDA, CASRN 335-76-2), perfluoroundecanoic acid (PFUnA, CASRN 2058-94-8), and perfluorohexane sulfonic acid (PFHxS, CASRN 355-46-4). Each of the seven individuals has levels in excess of the NHANES mean for at least two of the other five PFCs, as shown by the enclosed table.

Actions taken by Solvay, including the submission of this report, should not be taken to mean that Solvay recognizes or admits there is any health issue with respect to the presence of PFNA or other PFCs in human serum at the detected levels or that Solvay is in any way responsible for these substances if they are found; other sources have contributed to ambient PFC levels in the environment.

If you have any questions or require additional information regarding this submission, please do not hesitate to contact me.

Sincerely,



Charles Jones  
Plant Manager  
Solvay Specialty Polymers USA, LLC

Enclosures

<sup>1</sup> EPA, "Toxic Substances Control Act (TSCA) Section 8(e) Substantial Risk Notifications—Frequent Questions" (Sept. 2006) (Q & A 2), available at <http://www.epa.gov/oppt/tsc8e/pubs/frequentlyaskedquestionsfaqs.html>.

<sup>2</sup> CDC, "Fourth National Report on Human Exposure to Environmental Chemicals, Updated Tables" (Feb. 2015), available at [http://www.cdc.gov/biomonitoring/pdf/FourthReport\\_UpdatedTables\\_Feb2015.pdf](http://www.cdc.gov/biomonitoring/pdf/FourthReport_UpdatedTables_Feb2015.pdf).

[Confidentiality claim removed]

Sample	PFNA (ug/L)	PFOA (ug/L)	PFOS (ug/L)	PFDA (ug/L)	PFUnA (ug/L)	PFHxS (ug/L)
Individual 1	<b>35</b>	<b>29.7</b>	<b>13.6</b>	U 0.5	U 0.5	<b>2.09</b>
Individual 2	<b>55.8</b>	<b>60.8</b>	<b>9.04</b>	U 0.5	U 0.5	<b>3.5</b>
Individual 3	<b>11.5</b>	<b>13.7</b>	2.9	U 0.5	U 0.5	U 1
Individual 4	<b>2.26</b>	<b>2.16</b>	<b>6.69</b>	U 0.5	U 0.5	U 1
Individual 5	<b>7.63</b>	<b>2.31</b>	<b>78.2</b>	<b>2.78</b>	<b>3.58</b>	<b>1.78</b>
Individual 6	<b>5.01</b>	1.61	<b>28</b>	<b>0.812</b>	<b>1.81</b>	1.01
Individual 7	<b>2.05</b>	1.3	<b>9.03</b>	U 0.5	<b>0.898</b>	U 1
NHANES Geometric Mean 2009-2010	1.26	3.07	9.32	0.279	0.172	1.66
NHANES Geometric Mean 2011-2012	0.881	2.08	6.31	0.199	--	1.28

**Bold** values exceed the NHANES geometric mean for the 2011-2012 survey period (2009-2010 for PFUnA, which did not have a 2011-2012 NHANES calculation)

"U" indicates value below the method quantitation limit

**Return Receipt**  
**Via Courier**

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April 21, 2016

**Attention Messenger:**

Please deliver to: U.S. Environmental Protection Agency at the address below.

Please file-stamp both sets of documents, and return the set stamped "Copy" to Keller and Heckman, attn.: Amanda Davis (202) 434-4283. Thank you

**Courier Address**

TSCA Confidential Business Information Center (7407M)  
WJC East; Room 6428; Attn: Section 8(e)  
U.S. Environmental Protection Agency

1201 Constitution Avenue, NW  
WJC East; Room 6428  
Washington, DC 20004-3302

**Return Address**

Keller and Heckman LLP  
1001 G Street NW, Suite 500 W  
Washington, D.C. 20001

LAW OFFICES  
**KELLER AND HECKMAN LLP**  
1001 G STREET, N.W.  
SUITE 500 WEST  
WASHINGTON, D.C. 20001

VIA HAND DELIVERY  
(Round-trip: return file-stamped copy to Keller and Heckman)

TSCA Confidential Business Information Center (7407M)  
WJC East; Room 6428; Attn: Section 8(e)  
U.S. Environmental Protection Agency

1201 Constitution Avenue, NW  
WJC East; Room 6428  
Washington, DC 20004-3302

2016 MAY 17 AM 6:00

**Writer's Direct Access**  
**John B. Dubeck**  
(202) 434-4125  
dubeck@khlaw.com

May 12, 2016

**Via Certified Mail**

TSCA Confidential Business Information Center (7407M)  
WJC East; Room 6428; Attn: Section 8(e)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460-0001

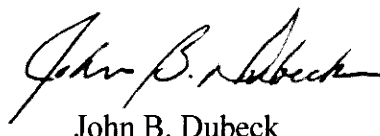
**Re: Addendum to CBIC Control No. 368682; TSCA 8(e) Submission for  
Chemical Abstracts Service Registry Numbers (CASRN) 375-95-1, 335-  
67-1, 1763-23-1, 335-76-2, 2058-94-8, and 355-46-4**

Dear Sir or Madam:

On behalf of our client, Solvay Specialty Polymers USA, LLC (Solvay), we are filing an "addendum" to a March 24, 2016, submission to the U.S. Environmental Protection Agency (EPA) that was made pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA) (15 U.S.C. § 2601 *et seq.*). This filing (CBIC Control No. 368682) concerns the substance perfluorononanoic acid (PFNA, CASRN 375-95-1) and several other perfluorinated chemicals (PFCs). Based on discussions with EPA staff in the Office of Pollution Prevention and Toxics, our client is withdrawing the confidential business information (CBI) claims for this submission. We have enclosed a copy of this submission with the CBI claims removed; the content of the submission is otherwise unmodified. The enclosed copy should replace the March 24, 2016, original as the primary copy on file with EPA.

If you have any questions or require additional information on this matter, please do not hesitate to contact me.

Sincerely,

  
John B. Dubeck

Enclosure



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2016 MAY 17 AM 6:01

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March 24, 2016

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[Confidentiality claim removed]

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March 24, 2016

Page 2

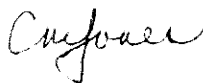
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Charles Jones  
Plant Manager  
Solvay Specialty Polymers USA, LLC

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[Confidentiality claim removed]

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LAW OFFICES  
**KELLER AND HECKMAN LLP**  
1001 G STREET, N.W.  
SUITE 500 WEST  
WASHINGTON, D.C. 20001



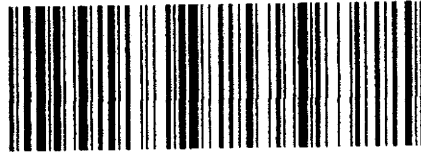
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